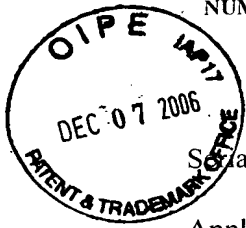


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Docket No. 4439-4026

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Serial No.: 10/511,693

Confirmation No.: 9184

Applicant(s): Masayuki AMAGAI, et al.

Group Art Unit: 1632

Examiner: Anoop Kumar Singh

Filed: October 14, 2004

Customer No.: 27123

For: DRUGS TO BE USED IN GENE THERAPY FOR RECESSIVELY TRANSMITTED  
GENETIC DISEASE

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Supplemental Information Disclosure Statement is filed in accordance with 37 C.F.R. §§1.56, 1.97 and 1.98. The items listed on Form PTO-1449, a copy of which is enclosed, are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

1. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:
2. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3. ☐ Any copy of the items listed on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in application Serial No. \_\_\_\_\_, filed \_\_\_\_\_.
4. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:  
☐ 37 C.F.R. §1.97(b)(1), within three months of the filing date of a national application other than a CPA; or

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- ☐ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application; or
- ☐ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits; or
- ☐ 37 C.F.R. §1.97(b)(4) before the mailing date of a first office action after the filing of an RCE under §1.114.
5. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.
6. ☒ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):
- ☐ A check in the amount of \$180.00 is enclosed in payment of the fee.
- ☒ Charge the fee to Deposit Account No. 13-4500, Order No. 4439-4026. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.
7. ☐ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:
- a. one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and
- b. the fee due under 37 C.F.R. §1.17(p) which is paid as set forth in paragraph 11 below.
8. ☐ This Information Disclosure Statement is being filed in compliance with:
- a. ☐ 37 C.F.R. §1.313(b)(3) or §1.313(c)(1), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue and fee pursuant to 37 C.F.R. §1.17(h);
- b. ☐ 37 C.F.R. §1.313(c)(2) or §1.313(c)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Request for Continued Examination (RCE) or a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue and fee pursuant to 37 C.F.R. §1.17(h).

- c. ☐ The fee due under 37 C.F.R. §§1.17(h) is paid as set forth in paragraph 11 below.
9. ☐ I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- ☐ I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
10. ☐ This document is accompanied by ☐ a Search Report ☐ Communication which was cited in a corresponding ☐ PCT or ☐ Foreign counterpart application
11. ☐ A check in the amount of \$ \_\_\_\_\_ is enclosed in payment of the fees due under 37 C.F.R. §§1.17(h) and 1.17(p).
- ☒ Charge the fees due under 37 C.F.R. §§1.17(h) and 1.17(p) to Deposit Account No. 13-4500, Order No. 4439-4026. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 13-4500, Order No. 4439-4026. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,  
MORGAN & FINNEGAN, L.L.P.

Dated: December 7, 2006

By: \_\_\_\_\_

*Evelyn M. Kwon*  
Evelyn M. Kwon  
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Docket No. 4439-4026

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Serial No.: 10/511,693 Confirmation No.: 9184  
Applicant(s): Masayuki AMAGAI, et al. Group Art Unit: 1632  
Examiner: Anoop Kumar Singh  
Filed: October 14, 2004  
Customer No.: 27123  
For: DRUGS TO BE USED IN GENE THERAPY FOR RECESSIVELY TRANSMITTED  
GENETIC DISEASE

**EXPRESS MAIL CERTIFICATE**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Express Mail Label No.: EV 825 711 051 US

Date of Deposit: December 7, 2006

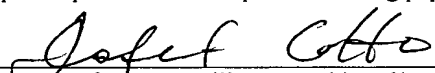
I hereby certify that the following attached paper(s) and/or fee

1. Supplemental Information Disclosure Statement (3 pages);
2. Form PTO-1449B (3 pages), with a copy of all 36 cited references;  
and
3. Return receipt postcard.

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated above and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Jafet N. Cotto

(Typed or printed name of person mailing papers(s) and/or fee)

  
(Signature of person mailing paper(s) and/or fee)

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## FORM PTO-1449B

INFORMATION DISCLOSURE  
CITATIONAttorney Docket:  
4439-4026Serial No.:  
10/511,693Applicant:  
Masayuki AMAGAI, et al.Filing Date:  
October 14, 2004Group Art Unit:  
1632

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	1.	Amagai M, Hashimoto T, Shimizu N, and Nishikawa T: "Absorption of pathogenic autoantibodies by the extracellular domain of pemphigus vulgaris antigen (Dsg3) produced by baculovirus," <i>J Clin Invest</i> , 94:59-67, July 1994.
	2.	Amagai M, Klaus-Kovtun V, and Stanley JR: "Autoantibodies against a novel epithelial cadherin in pemphigus vulgaris, a disease of cell adhesion," <i>Cell</i> , 67:869-877, November 29, 1991.
	3.	Amagai M, Koch PJ, Nishikawa T, and Stanley JR: "Pemphigus vulgaris antigen (Desmoglein 3) is localized in the lower epidermis, the site of blister formation in patients," <i>J Invest Dermatol</i> , 106:351-355, 1996.
	4.	Amagai M, Tsunoda K, Suzuki H, Nishifuji K, Koyasu S, and Nishikawa T: "Use of autoantigen-knockout mice in developing an active autoimmune disease model for pemphigus," <i>J Clin Invest</i> , 105:625-631, 2000.
	5.	Chen M, O'Toole EA, Muellenhoff M, Medina E, Kasahara N, and Woodley DT: "Development and characterization of a recombinant truncated type VIII collagen "minigene". Implication for gene therapy of dystrophic epidermolysis bullosa," <i>J Biol Chem</i> , 275(32):24429-24435, August 11, 2000.
	6.	Choate KA, Medalie DA, Morgan JR, and Khavari PA: "Corrective gene transfer in the human skin disorder lamellar ichthyosis," <i>Nat Med</i> , 2(11):1263-1267, November 1996.
	7.	Christensen R, Jensen UB, and Jensen TG: "Cutaneous gene therapy-an update," <i>Histochem Cell Biol</i> , 115:73-82, November 28, 2000.
	8.	Dai Y, Schwarz EM, Gu D, Zhang W-W, Sarvetnick N, and Verma IM: Cellular and humoral immune responses to adenoviral vectors containing factor IX gene: "Tolerization of factor IX and vector antigens allows for long-term expression," <i>Proc Natl Acad Sci</i> , 92:1401-1405, February 1995.
	9.	Datta SK, and Kalled SL: "CD40-CD40 ligand interaction in autoimmune disease," <i>Arthritis Rheum</i> , 40(10):1735-1745, October 1997.
	10.	Dellambra E, Vailly J, Pellegrini G, Bondanza S, Golisano O, Macchia C, Zambruno G, Meneguzzi G, and De Luca M: "Corrective transduction of human epidermal stem cells in laminin-5-dependent junctional epidermolysis bullosa," <i>Hum Gene Ther</i> , 9:1359-1370, June 10, 1998.
	11.	Freiberg RA, Choate KA, Deng H, Alperin ES, Shapiro LJ, and Khavari PA: "A model of corrective gene transfer in X-linked ichthyosis," <i>Hum Mol Genet</i> , 6(6):927-933, 1997.
	12.	Greenhalgh DA, Rothnagel JA, and Roop DR: "Epidermis: An attractive target tissue for gene therapy," <i>J Invest Dermatol</i> , 103:63S-69S, 1994.
	13.	Hengge U, Chan EF, Foster RA, Walker PS, and Vogel JC: "Cytokine gene expression in epidermis with biological effects following injection of naked DNA," <i>Nat Genet</i> , 10:161-166, June 1995.

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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<b>FORM PTO-1449B</b>  <b>INFORMATION DISCLOSURE</b> <b>CITATION</b>		Attorney Docket: 4439-4026	Serial No.: 10/511,693
		Applicant: Masayuki AMAGAI, et al.	
		Filing Date: October 14, 2004	Group Art Unit: 1632
<b>NON PATENT LITERATURE DOCUMENTS</b>			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	
	14.	Hengge UR, Walker PS, and Vogel JC: "Expression of naked DNA in human, pig, and mouse skin," <i>J Clin Invest</i> , 97(12):2911-6, June 1996.	
	15.	Ilan Y, Prakash R, Davidson A, Jona V, Droguette G, Horwitz MS, Chowdhury NR, and Chowdhury JR: "Oral tolerization to adenoviral antigens permits long-term gene expression using recombinant adenoviral vectors," <i>J Clin Invest</i> , 99(5):1098-1106, March 1997.	
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	21.	Koch PJ, Mahoney MG, Ishikawa H, Pulkkinen L, Uitto J, Shultz L, Murphy GF, Whitaker-Menezes D, and Stanley JR: "Targeted disruption of the pemphigus vulgaris antigen (desmoglein 3) gene in mice causes loss of keratinocyte cell adhesion with a phenotype similar to pemphigus vulgaris," <i>J Cell Biol</i> , 137(5):1091-1102, June 2, 1997.	
	22.	Larregina AT, and Falo LD: "Generating and regulating immune responses through cutaneous gene delivery," <i>Hum Gene Ther</i> , 11:2301-2305, November 1, 2000.	
	23.	Morrall N, O'Neal W, Zhou H, Langston C, and Beaudet A: "Immune responses to reporter proteins and high viral dose limit duration of expression with adenoviral vectors: comparison of E2a wild type and E2a deleted vectors," <i>Hum Gene Ther</i> , 8:1275-1286, July 1, 1997.	
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Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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<b>FORM PTO-1449B</b>  <b>INFORMATION DISCLOSURE</b> <b>CITATION</b>		Attorney Docket: 4439-4026	Serial No.: 10/511,693
		Applicant: Masayuki AMAGAI, et al.	
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	27.	Tripathy SK, Black HB, Goldwasser E, and Leiden JM: "Immune responses to transgene-encoded proteins limit the stability of gene expression after injection of replication-defective adenovirus vectors," <i>Nat Med</i> , 2(5):545-550, May 1996.	
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	31.	Vogel JC: "Nonviral skin gene therapy," <i>Hum Gene Ther</i> , 11:2253-2259, November 1, 2000.	
	32.	Yamada A, and Sayegh MH: "The CD154-CD40 costimulatory pathway in transplantation," <i>Transplantation</i> , 73(1):S36-S39, January 15, 2002.	
	33.	Yang Y, Su Q, Grewal IS, Schilz R, Flavell RA, and Wilson JM, "Transient subversion of CD40 ligand function diminishes immune responses to adenovirus vectors in mouse liver and lung tissues," <i>J Virol</i> , 70(9): 6370-6377, September 1996.	
	34.	Yao SN, Farjo A, Roessler BJ, Davidson BL, and Kurachi K, "Adenovirus-mediated transfer of human factor IX gene in immunodeficient and normal mice: Evidence for Prolonged Stability and Activity of the Transgene in Liver," <i>Viral Immunol</i> , 9(3):141-153, November 3, 1996.	
	35.	Zeng L, Sarasin A, and Mezzina M: "Retrovirus-mediated DNA repair gene transfer into xeroderma pigmentosum cells," <i>Cell Biol Toxicol</i> , 14:105-110, 1998.	
	36.	Spirito F, Meneguzzi G, Danos O, and Mezzina M: "Cutaneous gene transfer and therapy: the present and the future," <i>J Gene Med</i> , 3:21-31, December 22, 2000.	

Examiner Signature		Date Considered	
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